

AMENDED IN ASSEMBLY JANUARY 4, 2010

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 1370

Introduced by Assembly Member Solorio

February 27, 2009

~~An act to amend Section 111385 of the Health and Safety Code, relating to public health. An act to amend Section 4029 of, and to add Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacies, and making an appropriation therefor.~~

LEGISLATIVE COUNSEL'S DIGEST

AB 1370, as amended, Solorio. ~~Drugs and devices: labeling: expiration date: best before date. Centralized hospital packaging pharmacies.~~

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location. Under existing law, a hospital pharmacy, as defined, includes a pharmacy located outside of the hospital in another physical plant. However, as a condition of licensure by the board for these pharmacies, pharmaceutical services may only be provided to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located. A knowing violation of the Pharmacy Law is a crime.

This bill would authorize a centralized hospital packaging pharmacy, as defined, to prepare medications, by performing specified functions, for administration only to inpatients within its own general acute care

hospital and one or more general acute care hospitals if the hospitals are under common ownership. The bill would prohibit a person from conducting a centralized hospital packaging pharmacy without a specialty license from the board and would require applicants to apply annually to the board on forms developed by the board. The bill would condition both the issuance and renewal of a specialty license on a board inspection of the centralized hospital packaging pharmacy to ensure that the pharmacy is in compliance with the bill's provisions and regulations established by the board. The bill would impose specified issuance and annual renewal fees for a specialty license and because these fees would be deposited into the Pharmacy Board Contingent Fund, a continuously appropriated fund, the bill would make an appropriation.

The bill would impose various requirements on centralized hospital packaging pharmacies, including, but not limited to, that the expiration date for drugs prepared in advance of receipt of a patient specific prescription shall not exceed 72 hours, that medications be barcoded to be readable at the inpatient's bedside, and that medication labels contain specified information. The bill would make these pharmacies and pharmacists responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the packaging pharmacy. Because a knowing violation of these provisions would be a crime, the bill would impose a state-mandated local program.

~~Existing law, the Sherman Food, Drug, and Cosmetic Law, requires the State Department of Public Health to regulate manufacture, sale, labeling, and advertising activities related to food, drugs, devices, and cosmetics in conformity with the federal Food, Drug, and Cosmetic Act. A violation of these provisions is a crime.~~

~~Existing law classifies a drug or device as misbranded if the department determines that the drug or device is liable to deterioration and the drug or device is not packaged and labeled in a form and manner and set forth in regulations of the department.~~

~~This bill would require that the label contain a "best before" date in addition to the expiration date of the effectiveness of the drug or device. By expanding the definition of an existing crime, this bill would impose a state-mandated local program.~~

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: ~~no~~ yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 *SECTION 1. Section 4029 of the Business and Professions*
2 *Code is amended to read:*

3 4029. (a) “Hospital pharmacy” means and includes a
4 pharmacy, licensed by the board, located within any licensed
5 hospital, institution, or establishment that maintains and operates
6 organized facilities for the diagnosis, care, and treatment of human
7 illnesses to which persons may be admitted for overnight stay and
8 that meets all of the requirements of this chapter and the rules and
9 regulations of the board.

10 (b) A hospital pharmacy also includes a pharmacy that may be
11 located outside of the hospital, in another physical plant that is
12 regulated under a hospital’s consolidated license issued pursuant
13 to Section 1250.8 of the Health and Safety Code. As a condition
14 of licensure by the board, the pharmacy in another physical plant
15 shall provide pharmaceutical services only to registered hospital
16 patients who are on the premises of the same physical plant in
17 which the pharmacy is located, *except as provided in Article 7.6*
18 *(commencing with Section 4128)*. The pharmacy services provided
19 shall be directly related to the services or treatment plan
20 administered in the physical plant. Nothing in this ~~paragraph~~
21 *subdivision* shall be construed to restrict or expand the services
22 that a hospital pharmacy may provide.

23 *SEC. 2. Article 7.6 (commencing with Section 4128) is added*
24 *to Chapter 9 of Division 2 of the Business and Professions Code,*
25 *to read:*

26
27 *Article 7.6. Centralized Hospital Packaging Pharmacies*
28

29 4128. (a) *Notwithstanding Section 4029, a centralized hospital*
30 *packaging pharmacy may prepare medications, by performing the*
31 *following specialized functions, for administration only to*
32 *inpatients within its own general acute care hospital and one or*

1 more general acute care hospital if the hospitals are under common
2 ownership.

3 (1) Preparing unit dose packages for single administration to
4 inpatients from bulk containers, if each unit dose package is
5 barcoded to contain at least the information required by Section
6 4128.4.

7 (2) Preparing compounded unit dose drugs for parenteral
8 therapy for administration to inpatients, if each compounded unit
9 dose drug is barcoded to contain at least the information required
10 by Section 4128.4.

11 (3) Preparing compounded unit dose drugs for administration
12 to inpatients, if each unit dose package is barcoded to contain at
13 least the information required by Section 4128.4.

14 (b) For the purposes of this article, a “centralized hospital
15 packaging pharmacy” means a licensed hospital pharmacy located
16 within a general acute care hospital, as defined in subdivision (a)
17 of Section 1250 of the Health and Safety Code.

18 4128.1. (a) No person shall conduct a centralized hospital
19 packaging pharmacy unless it has obtained a specialty license
20 from the board.

21 (b) A licensed hospital pharmacy serving only its own inpatients
22 shall not be required to obtain a specialty license as described in
23 subdivision (a).

24 4128.2. (a) In addition to the pharmacy license requirement
25 described in Section 4110, a centralized hospital packaging
26 pharmacy shall obtain a specialty license from the board prior to
27 engaging in the functions described in Section 4128.

28 (b) An applicant seeking a specialty license pursuant to this
29 article shall apply to the board on forms established by the board.

30 (c) Before issuing the specialty license, the board shall inspect
31 the pharmacy and ensure that the pharmacy is in compliance with
32 this article and regulations established by the board.

33 (d) A license to perform the functions described in Section 4128
34 may only be issued to a pharmacy that is licensed by the board as
35 a hospital pharmacy.

36 (e) A license issued pursuant to this article shall be renewed
37 annually and is not transferrable.

38 (f) An applicant seeking renewal of a specialty license shall
39 apply to the board on forms established by the board.

1 (g) A license to perform the functions described in Section 4128
2 shall not be renewed until the pharmacy has been inspected by the
3 board and found to be in compliance with this article and
4 regulations established by the board.

5 (h) The fee for issuance or annual renewal of a centralized
6 hospital packaging pharmacy license shall be six hundred dollars
7 (\$600) and may be increased by the board to eight hundred dollars
8 (\$800).

9 4128.3. A centralized hospital packaging pharmacy may
10 prepare and store a limited quantity of the unit dose drugs
11 authorized by Section 4128 in advance of receipt of a patient
12 specific prescription in a quantity as is necessary to ensure
13 continuity of care for an identified population of inpatients of the
14 general acute care hospital based on a documented history of
15 prescriptions for that patient population. The expiration date for
16 these drugs shall not exceed 72 hours.

17 4128.4. Any unit dose medication produced by a centralized
18 hospital packaging pharmacy shall be barcoded to be readable at
19 the inpatient's bedside. A reading of the barcode shall display all
20 of the following:

- 21 (a) The date the medication was prepared.
- 22 (b) The components used in the drug product.
- 23 (c) The lot number or control number.
- 24 (d) The National Drug Code Directory number.
- 25 (e) The name of the centralized hospital packaging pharmacy.

26 4128.5. The label for each unit dose medication produced by
27 a centralized hospital packaging pharmacy shall contain all of the
28 following:

- 29 (a) The expiration date.
- 30 (b) The established name of the drug.
- 31 (c) The quantity of the active ingredient.
- 32 (d) Special storage or handling requirements.

33 4128.6. All compounding and packaging functions specified
34 in Section 4128 shall be performed only in the licensed centralized
35 hospital packaging pharmacy and that pharmacy shall comply
36 with all applicable regulations, including, but not limited to,
37 regulations regarding compounding and when appropriate, sterile
38 injectable compounding.

39 4128.7. A centralized hospital packaging pharmacy and the
40 pharmacists working in the pharmacy shall be responsible for the

1 integrity, potency, quality, and labeled strength of any unit dose
2 drug product prepared by the centralized hospital packaging
3 pharmacy.

4 SEC. 3. No reimbursement is required by this act pursuant to
5 Section 6 of Article XIII B of the California Constitution because
6 the only costs that may be incurred by a local agency or school
7 district will be incurred because this act creates a new crime or
8 infraction, eliminates a crime or infraction, or changes the penalty
9 for a crime or infraction, within the meaning of Section 17556 of
10 the Government Code, or changes the definition of a crime within
11 the meaning of Section 6 of Article XIII B of the California
12 Constitution.

13 ~~SECTION 1. Section 111385 of the Health and Safety Code~~
14 ~~is amended to read:~~

15 ~~111385. Any drug or device is misbranded if the department~~
16 ~~determines that the drug or device is liable to deterioration, unless~~
17 ~~it is packaged in that form and manner and its label bears a~~
18 ~~statement of the precautions, as the department, by regulation, may~~
19 ~~require as necessary for the protection of public health, including,~~
20 ~~but not limited to, "best before" date in addition to the expiration~~
21 ~~date of the effectiveness of the drug or device. The regulations~~
22 ~~shall not be established for any drug or device recognized in an~~
23 ~~official compendium, unless the department has informed the~~
24 ~~appropriate body, charged with the revision of the official~~
25 ~~compendium, of the need for that packaging or labeling~~
26 ~~requirements and that body has not prescribed the requirements~~
27 ~~in a reasonable length of time.~~

28 ~~SEC. 2. No reimbursement is required by this act pursuant to~~
29 ~~Section 6 of Article XIII B of the California Constitution because~~
30 ~~the only costs that may be incurred by a local agency or school~~
31 ~~district will be incurred because this act creates a new crime or~~
32 ~~infraction, eliminates a crime or infraction, or changes the penalty~~
33 ~~for a crime or infraction, within the meaning of Section 17556 of~~
34 ~~the Government Code, or changes the definition of a crime within~~
35 ~~the meaning of Section 6 of Article XIII B of the California~~
36 ~~Constitution.~~